REMARKS

Claims 32-45 and 49-56 were pending in the present application. Claims 32-45 and 49-56 have been canceled, without prejudice, and new claims 57-62 have been added. Accordingly, claims 57-62 will be pending upon entry of the instant amendment. Any cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to expedite prosecution of the application. Support for new claims 57-62 can be found throughout the specification and claims as originally filed. Specifically, support may be found at pages 7 and 8, beginning on line 34 of page 7, at page 10, lines 8-16, at page 25, lines 5-19, at page 26, lines 16-28, at page 46, beginning on line 29 and within Example 4 at page 82. No new matter has been added, and Applicants submit that all of the claims are now in condition for allowance.

Objections to the Specification

The Examiner has objected to the specification because "it contains blank spaces in several pages". Applicants have amended the specification in order to remove any such blank spaces. Therefore, Applicants respectfully request reconsideration and withdrawal of the foregoing objection.

The Rejection of Claims 49-52 under 35 U.S.C. §112, Second Paragraph, Should Be Withdrawn

Claims 49-52 are rejected under 35 U.S.C. § 112, second paragraph, as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention". Specifically, claims 49-52 were rejected because the claims did not specify that the polypeptides being detected had to first be labeled in order to detect the label. In the interest of expediting prosecution, and without acquiescing to the Examiner's rejection, Applicants have canceled claims 49-52, thereby obviating the 35 U.S.C. §112, second paragraph rejection of claims 49-52. Therefore, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

The Rejection of Claims 42-45 under 35 U.S.C. §112, First Paragraph, Should Be Withdrawn

Claims 42-45 are rejected under 35 U.S.C. § 112, first paragraph, because "the specification, while being enabling for a method of identifying a compound which binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:2, does not reasonably provide enablement for a method of identifying a compound which binds to a polypeptide comprising any contiguous 10 amino acids of SEQ ID NO:2."

Specifically, the Examiner states that "Claims 42-45 are so broad as to encompass any human galactosyltransferase (HGT) comprising 10 consecutive amino acids of SEQ ID NO:2." The Examiner also states that "Applicants do not make it clear that by reciting "fragments" they mean a sequence of amino acids of SEQ ID NO:2 which exhibits the claimed activity." Applicants respectfully traverse this rejection, however in the interest of expediting prosecution, and in no way acquiescing to the Examiner's rejection, Applicants have canceled claims 42-45 in favor of new claims 57-58.

Newly presented claims 57-58 recite fragments comprising at least 200 contiguous amino acids of SEQ ID NO:2, wherein the fragment has galactosyltransferase-1 activity. The limitations within these new claims are fully enabled within the specification as Applicants have provided teachings for every element needed for one of skill in the art to practice the claimed invention. Firstly, Applicants have taught that fragments of the polypeptide used in the claimed invention may include sequences of 200 or greater contiguous amino acids (refer to page 26, beginning at line 26). Secondly, Applicants have taught two domains within the galactosyltransferase-1 polypeptide which are conserved and essential for activity of the polypeptide, namely the transmembrane domain and the galactosyltransferase-1 domain (refer to pages 9 and 10, beginning on line 7 of page 9, page 81, lines 3-5 and figures 3 and 4). By having identified the regions necessary for activity, Applicants have taught which regions of the polypeptide are amenable to alterations as well as those which are not amenable to alterations. Thirdly, the specification teaches one how to generate functional variants by performing conservative substitutions within the polypeptide used in the claimed invention. As defined on page 20, "[c]onservative amino acid substitutions are made at one or more predicted non-essential amino acid residues. A "conservative amino acid substitution" is one in which the

amino acid residue is replaced with an amino acid residue having a similar side chain." The Applicants have also defined which of the amino acids have similar side chains, thereby providing a skilled artisan the necessary tools to generate functional variants of the polypeptide used in the claimed invention. Fourthly, not only have the Applicants provided the teachings for generating such functional variants, Applicants have provided an example of a specific fragment having at least 200 contiguous amino acids of SEQ ID NO:2 which exhibits the galactosyltransferase-1 activity, namely the galactosyltransferase family domain located at about residues 102-321 of SEQ ID NO:2 (refer to page 80, lines 23-26 and figure 3).

Finally, Applicants have provided teachings for one of skill in the art to be able to perform assays to determine whether or not specific sequences have the desired galactosytransferase-1 activity. As taught on page 10 of the specification, lines 8-16, such a galactosyltransferase-1 activity can include "the ability to form a glycosidic bond between molecules, *e.g.*, between UDP-galactose and N-acetylglucosamine (*e.g.*, N-acetylglucosamine on a polysaccharide or glycoprotein), in a cell (*e.g.*, in the Golgi complex (*e.g.*, the *trans* Golgi)); and the ability to regulate lactose homeostasis in a cell." Based on these activities, one can perform assays on specific sequences to determine whether or not such sequences have the desired biological activities. Such assays include, for example, assays which monitor intracellular or extracellular UDP-galactose, UMP-galactose, N-acetylglucosamine, or N-acetyllactosamine concentration; glycoprotein synthesis; or cellular growth or proliferation (refer to pages 50 and 51, beginning on line 34 of page 50). Performing such assays to determine whether or not a fragment of SEQ ID NO:2 has the desired properties would not constitute undue experimentation. Therefore, Applicants have provided all of the necessary information to enable one of skill in the art to 1) identify regions within the polypeptide used in the claimed invention which may be altered while maintaining activity; 2) generate fragments; and 3) perform assays to determine whether or not the sequences generated do in fact have the desired galactosyltransferase-1 activity.

Therefore, contrary to the Examiner's assertions, Applicants have provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of newly added claims 57-58. Therefore,

Applicants respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. § 112, first paragraph rejection over claims 42-45.

The Rejection of Claims 42-45 under 35 U.S.C. §112, First Paragraph, Should Be Withdrawn

Claims 42-45 are rejected under 35 U.S.C. § 112, first paragraph, as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

Specifically, the Examiner states that "[t]he claims are directed to a method using a genus of polypeptide fragments of SEQ ID NO:2 that have not been disclosed in the specification." Applicants respectfully traverse this rejection, however in the interest of expediting prosecution, and in no way acquiescing to the Examiner's rejection, Applicants have canceled claims 42-45 in favor of new claims 57-58.

As recited above, newly presented claims 57-58 recite fragments comprising at least 200 contiguous amino acids of SEQ ID NO:2, wherein the fragment has galactosyltransferase-1 activity. In light of these newly presented claims, Applicants traverse the Examiner's rejection and argue that they were in possession of the claimed invention at the time of filing for the reasons discussed below.

The Examiner is of the opinion that Applicants had not disclosed the claimed genus of polypeptide fragments of SEQ ID NO:2 in the specification and hence were not entitled to such genus claims. The Examiner also states that "[w]hen there is substantial variation within the genus (i.e., a fragment which means either a single amino acid or two amino acids etc. may or may not have the desired activity of the polypeptide), one must describe a sufficient variety of species to reflect the variation within the genus." Contrary to the Examiner's assertion, the specification not only provides the sequence of the polypeptide used in the claimed invention (SEQ ID NO:2), but also provides a fragment that falls within the scope of the new claims, namely the galactosyltransferase-1 domain, as well as extensive teachings as discussed above, to obtain other functionally active fragments which fall within the scope of the new claims. Therefore, by having provided the full length sequence of the polypeptide used in the claimed

invention, a functional fragment of the polypeptide used in the claimed invention having the desired activity and an enabling disclosure for obtaining other such functional sequences, Applicants have provided the necessary teachings to demonstrate that they were in possession of the claimed invention at the time of filing. Applicants, therefore, respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. § 112, first paragraph rejection over claims 42-45.

The Rejection of Claims 32-45 and 49-56 under 35 U.S.C. §103(a), Should Be Withdrawn

Claims 32-45 and 49-56 are rejected under 35 U.S.C. §103(a), as being unpatentable over Conklin et al (WO0144479A1). The Examiner states that "Conklin et al. teach the polypeptide with SEQ ID NO:2, identify it as a galactosyltransferase homolog and assign various properties to the polypeptide and list its role in cell physiology." The Examiner further states that

> "While the reference does not explicitly teach an identical assay for identifying binding compounds for the polypeptide, using the teachings of the above reference and combining it with well established methods for assaying binding compounds existing in the art, it would have been obvious to one of ordinary skill in the art to use the polypeptide sequence which matches 100% with SEQ ID NO:2 of the instant application and develop methods for identification of compounds which bind to the polypeptide."

Applicants respectfully traverse this rejection, however in the interest of expediting prosecution, and in no way acquiescing to the Examiner's rejection, Applicants have canceled claims 32-45 and 49-56 in favor of new claims 57-62.

Newly presented claims 57-62 recite a method for identifying a compound capable of treating a cellular growth or proliferation disorder, wherein the cellular growth or proliferation disorder is selected from the group consisting of lung cancer, breast cancer and colon cancer. Applicants have demonstrated within the specification (refer to Example 4 and figures 5-8) that the polypeptide used in the claimed invention is expressed at elevated levels in lung cancer samples vs. normal lung samples, in breast cancer sample vs. normal breast samples and in colon cancer samples vs. normal colon samples. Conklin et al. do not teach that their molecule is expressed within these types of cells.

Therefore, it could not have been obvious to one of ordinary skill in the relevant art to identify compounds capable of treating a cellular growth or proliferation disorder, wherein the cellular growth or proliferation disorder is selected from the group consisting of lung cancer, breast cancer and colon cancer, using the teachings of Conklin et al. Therefore, Applicants respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. §103(a) rejection.

CONCLUSIONS

In view of the amendments and remarks made herein, Applicants respectfully submit that the objections and rejections presented by the Examiner are now overcome and that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is believed that this paper is being filed timely and that a one month extension of time is required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

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